IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMERICAN SALES COMPANY, on behalf of themselves and all others similarly situated,	)	Civil Action No.
Plaintiffs,	)	**JURY TRIAL DEMANDED**
v.	)	
ASTRAZENECA AB; AKTIEBOLAGET HASSLE; and ASTRAZENECA LP,	)	
Defendants.	)	

CLASS ACTION COMPLAINT

Plaintiff American Sales Company, on behalf of itself and the class of direct purchasers as defined below, upon personal knowledge as to facts pertaining to itself, and upon information and belief and upon the investigation of counsel as to all other matters, alleges as follows:

NATURE OF THE CASE

1. This is a nationwide class action alleging violations of federal antitrust law arising from the manufacture and marketing of the brand-name drug Toprol XL ("Toprol"), an extended-release heart medication. The generic name for the active ingredient in Toprol is metoprolol succinate. Toprol had U.S. sales of approximately $1.29 billion for the year 2005.

2. As alleged in greater detail herein, Defendants unlawfully maintained a monopoly in the relevant market by committing fraud and/or inequitable conduct before the United States Patent and Trademark Office ("PTO") in order to obtain U.S. Patent No. 5,001,161 (the "'161 patent") and 5,081,154 (the "'154 patent") which, in the absence of the fraud, would not have issued. Defendants then improperly listed the fraudulently obtained patent in the publication of the Federal Drug Administration ("FDA") known as the *Orange Book* in order to be able to assert patent infringement claims against, and block the market entry of, any potential competitor

who sought to market a competing generic version of Toprol. Knowing that the '161 and '154 patents were obtained by fraud and/or inequitable conduct, and were otherwise invalid, Defendants initiated patent infringement actions against at least three potential generic competitors, knowing that filing such litigation would automatically prohibit the FDA from granting approval to any of the generic manufacturers for up to 30 months.

3. By its unlawful acts, Defendants unreasonably restrained, suppressed, and eliminated competition in the market for Toprol and its generic equivalents; and illegally maintained its monopoly in the market for Toprol and its generic equivalents. As a result of Defendants' conduct, Plaintiff and the Class (as defined herein) paid millions of dollars for Toprol at supra-competitive prices that it would not have paid had competing and/or generic versions of the drug been available.

4. Plaintiff, on behalf of itself and all others who are direct purchasers of Toprol, seeks damages from Defendants based on allegations of monopolization of, and an attempt to monopolize, the market for Toprol and its generic bioequivalents, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

JURISDICTION AND VENUE

5. This action is brought under Section 4 and 16 of the Clayton Act, 15 U.S.C. § 15, to redress violations of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 15.

6. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) because Defendants transact business, are found, and/or have agents in this district; and

because a substantial portion of the affected trade and commerce described below has been carried out in this district.

7. The illegal monopolization and attempt to monopolize the market for Toprol and generic versions of Toprol, as alleged herein, have substantially affected interstate and foreign commerce.

RELEVANT MARKET

8. As to the claims so requiring, the relevant product market is the market for the manufacture and sale of Toprol, metoprolol succinate, and all generic bioequivalents rated "AB" by the FDA. The relevant geographic markets are the United States and its territories as a whole. At all relevant times, Defendants' market share in the relevant product and geographic markets was 100%.

PARTIES

9. Plaintiff American Sales Company ("ASC"), is a corporation organized and existing under the laws of the State of New York and having its principal place of business in Lancaster, New York. ASC purchased Toprol from one or more of the Defendants and/or their affiliates during the Class Period as defined below, and suffered injury as a result of Defendants' conduct.

10. Defendant AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at Sodertalje, Sweden. AstraZeneca AB was formerly known as Astra Aktiebolaget.

11. Defendant Aktiebolaget Hassle ("Hassle") is a company organized and existing under the laws of Sweden, having its principal place of business at Molndal, Sweden.

12. Defendant AstraZeneca LP is a limited partnership organized under the laws of Delaware, with its principal place of business in Wilmington, Delaware.

INTERSTATE TRADE AND COMMERCE

13. During all or part of the Class Period, one or more Defendants manufactured and sold substantial amounts of Toprol in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

14. At all material times, Toprol manufactured and sold by one or more Defendants was shipped across state lines and sold to customers located outside its state of manufacture.

15. During all or part of the Class Period (defined below), Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Toprol.

16. In furtherance of its efforts to monopolize and/or restrain competition in the market for Toprol and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

17. Defendants' efforts to monopolize and restrain competition in the market for Toprol alleged herein has substantially affected interstate and foreign commerce.

FACTUAL ALLEGATIONS

A. Brand-Name Drugs vs. Generic Drugs

18. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. The U.S. market accounts for more than 40% of the world's prescription pharmaceutical revenues. The cost of prescription drugs in the United

States has been rising at a rate of 14% to 18% per year, and the cost of drugs dispensed in the United States for the year 2001 was in the range of $160 billion to $170 billion.

19. The availability of generic drugs has been one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which also must be approved by the FDA, have the same active chemical composition and provide the same therapeutic effects as the pioneer brand-name drugs upon which they are modeled. The FDA will assign an "AB" rating to generic drugs that are bioequivalent to pioneer or brand-name drugs.

20. Generic drugs are normally priced substantially below the brand-name drugs to which they are bioequivalent. A 1998 study conducted by the Congressional Budget Office (the "CBO") concluded that generic drugs save consumers and third-party payors between $8 billion and $10 billion a year. A report prepared by the Government Accounting Office in August 2000 observed, "Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs."

21. The Federal Trade Commission ("FTC") estimates that the first generic manufacturer to enter the market typically charges between 70% and 80% of the price of the brand-name drug. As additional manufacturers bring generic versions of the drug to market, the price continues to drop.

22. A brand-name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition, even if the brand-name manufacturer lowers prices to meet competition. The 1998 CBO study estimates that generic drugs capture at least 44% of the brand-name drug's market share in just the first year of sale.

B. The Federal Scheme For Approval Of Pioneer Drugs

23. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "Act"), approval by the FDA is required before a company may begin selling a new drug. Pre-market approval for a new drug, often referred to as a "pioneer" or "brand-name" drug, must be sought by filing a New Drug Application ("NDA") with the FDA, demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are typically (but not necessarily) covered by patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the United States for the duration of the patents involved, plus any extension of the original patent period (the "FDA Exclusivity Period") granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 ("Hatch-Waxman Act").

24. In addition to information on safety and efficacy, NDA applicants must submit to the FDA a list of all "prior art," as well as patents that claim the drug for which FDA approval is being sought or that claim a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted. "Prior art" is the term used in patent law to refer to that body of previous knowledge and technology against which a patent application is judged to determine whether the claim is sufficiently novel to merit patent protection. When the NDA is approved, the FDA "shall publish" the patent information submitted by the NDA applicant. 21 U.S.C. § 355(b)(1).

25. Once the NDA is approved, the FDA lists any patents referenced as part of the NDA application process in a publication known as the *Approved Drug Products With Therapeutic Equivalence Evaluations*. This publication is commonly called the "*Orange Book*."

26. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be dispensed by a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-related generic version of that pioneer drug which has been approved by the FDA is available.

C. Prescriptions for Generic Drugs

27. Generic drugs are drugs that the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating.

28. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing the branded drug, or the AB-rated generic at a lower price.

29. Once a physician writes a prescription for a brand-name drug such as Toprol, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs which carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug.

D. Abbreviated New Drug Applications For Generic Drugs

30. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. Consumers benefit from the choice and competition. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an Abbreviated New Drug Application ("ANDA"), which incorporates by reference the safety and effectiveness data developed and previously submitted by the manufacturer of the original, pioneer drug. The Hatch-Waxman Act also provides an economic incentive to the first ANDA filer for a particular generic drug: a 180-day statutory period of market exclusivity, during which time the manufacturer has the right to market its drug free from competition from other generic manufacturers.

31. The ANDA must include information concerning the applicant's position *vis-a-vis* the patent that the pioneer drug manufacturer claims applies to the drug. Therefore, the ANDA filer must make one of four certifications:

I. that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");

II. that the patent for the pioneer drug has expired (a "Paragraph II Certification");

III. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

IV. that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV Certifications.

32. If the ANDA contains a Paragraph IV Certification, the ANDA applicant must provide notice to the owner of each patent that is referred to in the certification, and to the holder of the approved NDA to which the ANDA refers. *See* 21 U.S.C. § 355(j)(2)(B)(i). The notice must include a detailed statement of the factual and legal basis for the ANDA applicant's assertion that the patent is not valid or will not be infringed by the generic product. *See id.*; 21 C.F.R. § 314.95.

33. The brand-name drug patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has 45 days to initiate a patent infringement suit against the applicant. *See* 21 U.S.C. § 355(j)(5)(5)(iii). If no action is initiated within 45 days, the process for FDA approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the ANDA is automatically postponed until the earliest of the expiration of the patents, the expiration of 30 months from the patent holder's receipt of notice of the Paragraph IV Certification, or a final judicial determination of non-infringement.

34. Accordingly, brand-name drug patent holders need only to file a patent infringement lawsuit within 45 days of receipt of Paragraph IV Certification in order to

automatically block an ANDA applicant's generic drug from entering the market for up to 30 months.

35. An improper Orange Book listing also has additional anti-competitive effects because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of exclusivity in relation to other generic manufacturers. 21 U.S.C. 355(j)(5)(B)(iv). This 180 day exclusivity against other generic competitors is awarded to the first Paragraph 1V filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV certification. Absent an improper Orange Book listing, no Paragraph IV certification would be required and, thus, no generic company would receive 180-day exclusivity.

E. Defendants' Conduct In Obtaining an Unlawful Monopoly

1. The Patents Are Invalid for Double Patenting

36. On or about October 25, 1988, the PTO issued patent number 4,780,318 (the "'318 patent"), assigned to Lejus Medical Aktiebolag. The '318 patent concerned a drug formulation that allows the delivery of active drugs to the small intestine. Claim 8 of this patent includes a delivery formulation for metoprolol succinate. In the "Detailed Description of the Invention," the patent described the use of an outer and inner layer used in order to achieve "a slow but controlled release of the therapeutically active compound from the core by defusion through the defusion membrane [which] occurs due the difference in concentrations on each side of said membrane." When read in conjunction with Claims 6 and 7 of the patent application, it is clear that Claim 8 refers to a particular type of formulation which allows the slow and controlled release of metoprolol succinate in or near the colon.

37. The '318 patent expired on or about January 10, 2005.

38. On or about March 25, 1998, an application was filed with the PTO for what ultimately became the '161 patent, which issued on March 19, 1991, and was assigned to Hassle.

39. The sole claim of the '161 patent was "a sustained release pharmaceutical composition comprising metoprolol succinate together with a pharmaceutically acceptable carrier." The '161 patent was issued on or about .

40. Patent law includes a judicially created doctrine called "nonstatutory double patenting" which prevents the issuance of a patent on claims that are nearly identical to claims in an earlier patent. This doctrine is designed to prevent patent applicants from extending their patent term for an invention beyond the statutory limits by claiming a mere obvious variant of the claims in the prior patent.

41. A comparison of the two patents demonstrates that whereas Claim 8 of the '318 patent refers to a particular type of a controlled release formulation of metoprolol succinate, the claim of the '161 patent is a broad claim to any controlled release formulation of metoprolol succinate. Thus, the second, broader claim contained in the '161 patent is invalid because it was anticipated by, and therefore not patently distinct from, the earlier, narrower claim of the '318 patent. Consequently, the '161 patent was and is invalid.

42. On September 28, 1990, an application was filed for what ultimately became the '154 patent, which issued on January 14, 1992, and was assigned to Hassle. The only claim in the '154 patent is metoprolol succinate. Thus, the invention is the composition itself.

43. Thus, whereas Claim 8 of the '318 patent was directed to certain pharmaceutical compositions containing metoprolol succinate, the '154 patent broadly claimed any

pharmaceutical compositions containing any metoprolol succinate. Again, the claim of the '154 patent is anticipated by Claim 8 of the '318 patent, and the '154 patent is therefore void for double patenting because it is not distinct from the original patent.

2. The '161 Patent is invalid as anticipated

44. An application for a Swedish patent SE 8400085 was published on July 17, 1985. The Swedish application disclosed, among other things, the type of sustained release of metoprolol succinate that ultimately became Claim 8 of the 318 patent. The disclosure of the information in the Swedish patent anticipated the more general claim of sustained release in metoprolol succinate which is the invention of the '161 patent.

45. Because the Swedish patent application was published more than one year before the 161 patent application was filed, it constituted prior art, and the '161 patent is therefore invalid under 35 U.S.C. § 102 (b).

3. **Defendants Committed Inequitable Conduct on the PTO**

46. Rules governing patent prosecution impose a duty of candor and good faith on those dealing with the PTO, "which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56. The rule provides that:

> Information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.

47. A patent is invalid if it is obtained through inequitable conduct committed before the PTO. Inequitable conduct includes affirmative misrepresentations of material fact, failure to disclose material information, and/or submission of false material information coupled with the intent to deceive.

48. Because it is a critical requirement for obtaining a patent, the issue of inventorship is highly material in the patent prosecution process. Conduct that would mislead the PTO as to the identity of the inventors of a patent, or conduct that fails to disclose information about a dispute concerning the inventor, is highly material to the question of inequitable conduct because of the applicant's duty of candor and disclosure. Disputes concerning inventorship are material information that must be disclosed to the PTO. *See* Manual of Patent Examining Procedure §2001.06(c) and §2004.

49. The chemical compound metoprolol was invented in the 1960s at Defendant Hassle, which at that time was a Swedish pharmaceutical research and development company located in Molndal, Sweden.

50. In 1971, an chemist named Toivo Nitenberg working for Defendants or their affiliate synthesized metoprolol succinate. At that time, it was believed that metoprolol would be useful in the treatment of heart disease.

51. Defendants never disclosed to the PTO that there had been a dispute between Defendants and another Swedish pharmaceutical research and development company named Lejus Medical over who invented metoprolol succinate.

52. On January 10, 1984, Lejus filed patent application SE 8400085 with the Swedish Patent Office. The application was published on July 17, 1985.

53. When the Swedish patent application was first published, Defendants took the position that metoprolol succinate had been invented by its employee, Toivo Nitenberg, and that the extended release dosage formulation of metoprolol succinate was also its invention.

54. On October 21, 1985, Astra filed an action in the Swedish Patent Office, asserting that metoprolol succinate had not been invented by Curt Appelgren and Eva Eskilsson, the scientists at Lejus, but had been invented by Nitenberg at Astra.

55. As part of a negotiated resolution of this dispute, Lejus agreed to file new patent applications on the metoprolol succinate invention and then assign the applications to Astra. In exchange, Astra agreed to withdraw its ownership claim with the Swedish Patent Office, which asserted that Nitenberg was the actual and sole inventor of metoprolol succinate.

56. On March 25, 1998, Lejus filed U.S. patent application No. 172,897 which became the '161 patent. The application named Appelgren and Eskilsson as the inventors of metoprolol succinate. The application was filed as a continuation-in-part of U.S. patent application No. 690,197, which ultimately became the '318 patent. By filing it in this way, the '897 application was entitled to a priority to the earlier filing date of the '197 application, filed on January 10, 1985. With this priority, Defendants would be able to avoid a potential problem of the prior art revealed in the publication of EP 148811, on July 17, 1985, in Sweden.

57. At no time did defendants disclose to the PTO that the position they took in support of the '161 patent as to the identity of the inventor was directly contrary to the position they had taken before the Swedish Patent Office. Whereas in Sweden, Defendants had claimed that Nitenberg had been the sole inventor of the metoprolol succinate, in the U.S. PTO they falsely and knowingly stated that the inventors were Appelgren and Eskilsson. This knowing and

intentional misrepresentation was made to avoid the possible rejection of the patent application on the grounds that the publication of the Lejus application to the Swedish patent office would constitute prior art. Had the PTO known the truth, it would not have issued the '161 patent.

58. Even if defendants had not submitted false information to the PTO regarding the identity of the inventors, their failure to disclose material facts as to the dispute over inventorship constituted inequitable conduct which precluded enforcement of the patent as a matter of law.

4. Defendants File Sham Litigation Against Generic Manufacturers

59. KV Pharmaceutical Company ("KV") submitted an ANDA to obtain FDA approval to engage in the commercial manufacture, use and sale of a generic extended release formulation of meroprolol succinate prior to the expiration of the '161 and '154 patents. KV's ANDA contained a Paragraph IV Certification that the '161 and '154 patents were invalid and/or unenforceable.

60. Defendants filed a timely suit in the United States District Court for the Eastern District of Missouri, asserting that KV infringed the '161 and '154 patents. KV asserted counterclaims for patent invalidity and non-infringement. Defendants, with full knowledge that the '161 patent had been procured by fraud and was unenforceable, and with the full knowledge that the '161 and '154 patents were invalid because they constituted double patenting and were anticipated by prior art, proceeded with the baseless patent infringement litigation in order to invoke the 30-month Hatch-Waxman stay. This conduct had the effect of preventing generic versions of Toprol from coming to market and consequently of illegally extending Defendants' monopoly on Toprol while the litigation progressed.

61. Andrx Pharmaceuticals LLC and Andrx Corporation ("Andrx") submitted an ANDA to obtain FDA approval to engage in the commercial manufacture, use and sale of a generic extended release formulation of meroprolol succinate prior to the expiration of the '161 and '154 patents. Andrx's ANDA contained a Paragraph IV Certification that the '161 and '154 patents were invalid and/or unenforceable.

62. Defendants filed a timely suit in the United States District Court for the District of Delaware, asserting that KV infringed the '161 and '154 patents. Andrx asserted counterclaims for patent invalidity and non-infringement. Defendants, with full knowledge that the '161 patent had been procured by fraud and was unenforceable, and with the full knowledge that the '161 and '154 patents were invalid because they constituted double patenting and were anticipated by prior art, proceeded with the baseless patent infringement litigation in order to invoke the 30-month Hatch-Waxman stay. This conduct had the effect of preventing generic versions of Toprol from coming to market and consequently of illegally extending Defendants' monopoly on Toprol while the litigation progressed.

63. Eon Labs, Inc. ("Eon") submitted an ANDA to obtain FDA approval to engage in the commercial manufacture, use and sale of a generic extended release formulation of meroprolol succinate prior to the expiration of the '161 and '154 patents. KV's ANDA contained a Paragraph IV Certification that the '161 and '154 patents were invalid and/or unenforceable.

64. Defendants filed a timely suit in the United States District Court for the District of Delaware, asserting that KV infringed the '161 and '154 patents. KV asserted counterclaims for patent invalidity and non-infringement. Defendants, with full knowledge that the '161 patent had

been procured by fraud and was unenforceable, and with the full knowledge that the '161 and '154 patents were invalid because they constituted double patenting and were anticipated by prior art, proceeded with the baseless patent infringement litigation in order to invoke the 30-month Hatch-Waxman stay. This conduct had the effect of preventing generic versions of Toprol from coming to market and consequently of illegally extending Defendants' monopoly on Toprol while the litigation progressed.

65. All of the patent infringement cases were consolidated in the Eastern District of Missouri. *In re Metoprolol Succinate Patent Litig.*, MDL Docket No. 1620 (E.D. Mo.).

66. In a Memorandum and Order dated January 17, 2006, the district court in Missouri held by clear and convincing evidence that Defendants' '161 and '154 patents were invalid on the basis of double patenting over the '318 patent. The court further found by clear and convincing evidence that the '161 and '154 patents were unenforceable based on Defendants' inequitable conduct before the PTO in failing to disclose the dispute with Lejus over the identity of the inventors.

67. Accordingly, the district court in Missouri granted the generic manufacturers' motion for summary judgment and denied Defendants' motion for summary judgment.

68. Defendants' litigation against the generic manufacturers was objectively baseless and was brought solely for the anticompetitive purpose of delaying generic competition.

EFFECTS ON COMPETITION

69. Defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Defendants to sell Toprol at supra-competitive prices, without being subject to generic

competition. But for Defendants' illegal conduct, generic competitors would have begun marketing generic versions of Toprol products much sooner.

70. By preventing generic competitors from entering the market, Defendants injured Plaintiff by causing it to pay more for Toprol than they otherwise would have paid. Defendants' unlawful conduct deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to preserve.

71. Throughout the course of the proceedings before the PTO and for much of the litigation of the infringement action, Defendants knowingly, willfully and fraudulently concealed the true facts about their misrepresentations to the PTO in order to wrongfully obtain the '161 and '154 patents and to wrongfully prevent and discourage lawful competition with their brand name product Toprol, in the manner more specifically described herein.

72. This fraudulent concealment as described above prevented Plaintiff and the Class from learning the truth about Defendants' illegal conduct, which would have allowed earlier actions to be commenced. At all times, Plaintiff was kept in ignorance of the information necessary to know that Defendants had engaged in wrongful conduct or that Plaintiff had been harmed by such conduct.

CLASS ACTION ALLEGATIONS

73. Plaintiff brings this action on behalf of itself and as representative of a Class defined as follows:

> All persons or entities throughout the United States and its territories who purchased Toprol from Defendants and/or their affiliates during the period January 10, 2005, to the present ("the Class Period").

Excluded from the Class are all Defendants, their officers, subsidiaries and affiliates; all government entities; and all persons or entities that purchased Toprol from entities other than Defendants and their affiliates.

74. Plaintiff seeks class certification pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure.

75. The Class is so numerous that joinder is impracticable.

76. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual members, in part because Defendants have acted and refused to act on grounds generally applicable to the entire Class. Such conduct includes the Defendants' exclusionary and anti-competitive efforts to mislead the PTO, and the filing of sham litigation for the sole purpose of monopolizing and attempting to monopolize the market for Toprol.

77. Questions of law and fact common to the Class include:

(a) whether the '161 and '154 patents were invalid due to double patenting over the '318 patent;

(b) whether the '161 and '154 patents were invalid due to the existence of prior art;

(c) whether the '398 patent described herein was obtained through fraud or inequitable conduct;

(d) whether Defendants' litigation asserting infringement of its patents described herein was baseless;

(e) whether Defendants' actions illegally maintained its monopoly power;

(f) whether Defendants engaged in sham litigation for the purpose of preventing competition;

(g) whether Defendants have monopolized and attempted to monopolize the market for Toprol and generic bio-equivalents to Toprol;

(h) whether Defendants intentionally and unlawfully excluded competitors and potential competitors from the market for Toprol and generic bio-equivalents to Toprol;

(i) whether Plaintiffs and the Class have been damaged and the aggregate amount of damages.

78. Plaintiff's claims are typical of the members of the Class, in that Plaintiff purchased Toprol directly from Defendants and/or their affiliates. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

79. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiff are not antagonistic to those of the Class. In addition, Plaintiff is represented by counsel who are experienced and competent in the prosecution of complex class action antitrust litigation.

80. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress

for claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

81. Plaintiff knows of no difficulty to be encountered by litigating of this action that would preclude its maintenance as a class action.

COUNT I

FOR DAMAGES UNDER SECTION 2 OF THE SHERMAN ACT

82. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

83. As described above, Defendants knowingly and willfully engaged in a course of conduct designated to improperly obtain and extend their monopoly power in the Relevant Market. This course of conduct included, *inter alia*, the following acts: (i) the intentional submission of false patent information to the FDA; (ii) inequitable conduct before the PTO; and (iii) the prosecution of baseless, sham patent litigation against a potential generic manufacturer. The result of Defendants' unlawful conduct has been to obtain and extend their monopoly.

84. Defendants' infringement action against the generic manufacturers constituted sham litigation, in that the suit was objectively baseless due to, *inter alia*, the presence of the prior art and the inequitable conduct which rendered the '161 patent unenforceable; and in that Defendants' motivation in bringing the actions was to directly interfere with the ability of any generic manufacturers to market less expensive generic versions of Toprol that would compete with the brand-name product.

85. Defendants intentionally and wrongfully created and maintained a monopoly power in the Relevant Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

86. Plaintiff and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violation alleged in this Count. Their injury consists of being deprived of the ability to purchase Toprol at competitive prices The injury to Plaintiff and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct.

87. Plaintiff and the Class seek treble damages based on the overcharges paid by them to Defendants. The full amount of such damages are presently unknown and will be determined after discovery and upon proof at trial.

WHEREFORE, Plaintiff prays that:

(a) the Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure; and declare Plaintiff as the representative of the Class;

(b) the conduct alleged herein be declared, adjudged and decreed to be in violation of Section 2 of the Sherman Act;

(c) Plaintiff and each member of the Class be awarded treble damages; including interest;

(f) Plaintiff and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law;

(g) Plaintiff and the Class be granted such other and further as the Court deems just and necessary.

JURY DEMANDED

Plaintiff demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Dated: January _____, 2006

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JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
American Sales Company, on behalf of themselves and all others similarly situated

(b) County of Residence of First Listed Plaintiff Erie County, NY
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Jeffrey S. Goddess, Rosenthal, Monhait Gross & Goddess, PA, PO Box 1070, Wilmington, DE 19899 (302) 656-4433

DEFENDANTS
Astrazeneca AB; Aktiebolaget Hassle; and Astrazeneca LP

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☒ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881	PROPERTY RIGHTS	☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	☐ 820 Copyrights	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 830 Patent	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 840 Trademark	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health		☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other		☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 862 Black Lung (923)	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 863 DIWC/DIWW (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	☐ 864 SSID Title XVI	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 865 RSI (405(g))	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty		☐ 871 IRS—Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other			☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights			☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
Sherman Act, 15 U.S.C. §2. Civil antitrust action in connection with
Brief description of cause: monopolization of market for the drug metoprolol succinate (sold as "Toprol".

VII. REQUESTED IN COMPLAINT: ☒ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND $ CHECK YES only if demanded in complaint: JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER 06-052 UNA

DATE 1/31/06 SIGNATURE OF ATTORNEY OF RECORD Jeffrey S. Goddess (No. 630) (302) 656-4433

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____